

EXHIBIT 5

Confidential - Subject to Further Confidentiality Review

Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

IN RE DEPAKOTE CASES:)
)
H.B., a minor, by STACY)
BARTOLINI, individually) Case No.
as parents and next) 12-cv-52-NJR-SCW
friend of H.B.,)
) Case No.
T.C., a minor, by KAYLA) 15-cv-702-NJR-SCW
ROSE MCGUINNESS,)
individually as parent)
and next friend of T.C.,)
)
E.R.G., a minor, by)
CHRISTINA RAQUEL,)
individually as parent)
and next friend of)
E.R.G.,)
)
PLAINTIFFS,)
)
VS.)
)
)
ABBOTT LABORATORIES,)
INC.,)
)
DEFENDANT.)

VIDEOTAPED DEPOSITION OF
GODFREY P. OAKLEY, JR., M.D.
APRIL 26, 2016

CONFIDENTIAL - SUBJECT TO FURTHER
CONFIDENTIALITY REVIEW

Confidential - Subject to Further Confidentiality Review

Page 89

1 A. I'm not sure I have 159. Do I have 159?

2 Q. Well, let me -- let's take just a minute and
3 see. Do we have a copy?

4 A. You think I have it. Okay. All right.

5 Sorry. Yeah. Sorry. Thank you. That's 157 -- oh,
6 it is 159. Sorry. Okay.

7 Q. Okay. I'm going to show you a dear doctor
8 letter that Abbott sent out, 159, Exhibit 159, and
9 also their label change at that same date. Do you
10 have that exhibit in front of you, sir?

11 A. I do.

12 Q. And it talks about data collected in the
13 Rhone Valley area of France. Is that Lyon, France
14 that we've been talking about?

15 A. Yes.

16 Q. And it says there that the risk of valproic
17 acid exposed women having children with spina bifida
18 would be approximately 1.2 percent. And my question
19 is: Did Abbott in that letter convey that that was a
20 2,060 percent increase?

21 A. They did not.

22 Q. And do you think that was important
23 information that should have been included and
24 conveyed to physicians?

Confidential - Subject to Further Confidentiality Review

Page 90

1 MR. BALL: Object to the form and
2 foundation.

3 A. Yes, I believe it should have been.

4 Q. (By Mr. Williams) And in the -- and they
5 said that they've changed their label -- hang on just
6 a second. Okay. Doctor, do you see that they changed
7 their data -- data, they sent out this letter and they
8 changed their labels based upon a single preliminary
9 report. That's the Lyon data. Correct?

10 A. Yeah.

11 Q. And if we look at the label, did they ever
12 convey in the label the fact that it was a 2,060
13 increase in the rate of spina bifida?

14 A. I don't ever -- I don't see it here. If it's
15 here, I'm happy to see it, but the part that looks
16 like it should be I don't see.

17 Q. Okay. Now, in your opinion, a drug that has
18 a 2,060 percent -- causes a 2,060 percent increase in
19 spina bifida, should this drug have been removed from
20 the market?

21 MR. BALL: Object to the form and the
22 foundation and the argumentative nature of the
23 question. It's unfairly prejudicial.

24 A. So my -- my thought was that when we learned

Confidential - Subject to Further Confidentiality Review

Page 91

1 this drug was a -- was a powerful teratogen, that it
2 would be removed from the market. And then it wasn't
3 removed from the market. And I understood that there
4 were some neurologists who felt like this drug was
5 uniquely effective for some of their patients. And I
6 could understand the reason of keeping the drug on the
7 market for that limited group of people, but I would
8 have thought that there should be an active campaign
9 to decrease the number of fetuses that were exposed to
10 it. And that could be done two ways. One would be to
11 offer contraceptive advice, effective contraceptive
12 advice to women who might be taking this drug and were
13 sexually active, and the other would be to try to
14 minimize the number of women who actually took the
15 drug.

16 Q. (By Mr. Williams) And --

17 A. Women of reproductive age. Sorry.

18 Q. Do you think it should have been a drug of
19 last resort?

20 MR. BALL: Object to the form, the
21 foundation.

22 A. I would think that one should have
23 demonstrated other drugs don't work in most
24 circumstances.

Confidential - Subject to Further Confidentiality Review

Page 104

1 Q. And you charge \$500 per hour?

2 A. That is correct.

3 Q. And you charge \$500 per hour, you live in
4 Atlanta, we're taking this deposition here in Houston,
5 you charge \$500 per hour in traveling over here.

6 True?

7 A. Yes.

8 Q. And you charge \$500 an hour for your
9 preparation?

10 A. Yes.

11 Q. And you have done this on other occasions in
12 the past?

13 A. I have.

14 Q. And your total compensation to date from
15 working with these lawyers is approaching \$100,000.

16 True?

17 A. It's approaching that, but I don't know
18 exactly.

19 Q. Okay. But it's in that -- it's approaching
20 that. True?

21 A. Yes.

22 Q. Now, and just so we're also the clear, you
23 are here to talk about only the warning label that was
24 in effect in 1982. That's the only label that you've

Confidential - Subject to Further Confidentiality Review

Page 105

1 mentioned in your testimony here today. True?

2 A. That is true.

3 Q. And you have not and are not prepared to talk
4 about the warning labels that Abbott had for 1992,
5 1996, 2000, 2002, 2004, 2006, any of those other
6 times. True?

7 A. That is true.

8 Q. In fact, you haven't reviewed those and
9 studied those to be prepared to talk about them in
10 detail. True?

11 A. That is true.

12 Q. And you also have not been -- well, let me
13 back up. You worked for the CDC, and that's a
14 government agency as has been pointed out. Right?

15 A. That's correct.

16 Q. And that's a different government agency from
17 the FDA. True?

18 A. It most definitely is.

19 Q. And the CDC, I think you've told us, looks
20 into how to try to prevent disease. Right?

21 A. That's correct.

22 Q. And the FDA is in charge of drug safety and
23 drug labeling and drug warnings. Right?

24 A. That is true.

1 Q. Okay. That's the FDA's job. Right?

2 A. That's correct.

3 Q. Okay. And in terms -- there was some
4 discussion about the warning label that went out in
5 1982 to doctors. The FDA didn't ask you for your
6 input about that label. True?

7 A. I don't remember, actually, but I don't have
8 any recollection that they did, but we were
9 discussing, you know, the risk factors over those two
10 or three months before, but I don't remember having
11 any input into the final.

12 Q. And so the -- but the final label that went
13 out in 1982 after the data about spina bifida came out
14 from France, that dear doctor letter and that label
15 had to be approved by the FDA, not by the CDC. True?

16 MR. WILLIAMS: Objection. Foundation.
17 I'm not sure the witness has any personal knowledge of
18 this or knows about labeling regulations. I think he
19 just established that.

20 Q. (By Mr. Ball) Let me ask it this way: The
21 CDC had no role in approving the final label that was
22 sent out in 1982. True?

23 A. The CDC is not the agency that approves and
24 sends.

Confidential - Subject to Further Confidentiality Review

Page 154

1 Q. Yeah, let's talk about Dr. Holmes' registry.

2 He -- his -- his was started in 1996. Correct?

3 A. He worked on this problem from 20 years
4 before and had a difficult time getting funding to set
5 up those registries.

6 Q. But in 1996 various companies got together
7 and have provided funding for the North American
8 registry. True?

9 A. That is correct.

10 Q. And Abbott was one of those companies. True?

11 A. I believe that to be true, yes.

12 Q. And you said in your report that one of the
13 key findings of that study is the comparison of
14 Depakote versus other drugs. True?

15 A. Uh-huh.

16 Q. And you said that that information from the
17 registry could have been known earlier if that
18 registry had been started back in 1982. Correct?

19 A. Correct.

20 Q. All right. Can you tell me which
21 antiepileptic drugs were on the market in 1982?

22 A. It's easy to find.

23 Q. Okay.

24 A. Okay. And some of those were and some of

Confidential - Subject to Further Confidentiality Review

Page 192

1 bifida. Do you recall that series of questions?

2 A. I do.

3 Q. Do you have -- do you believe today that to
4 convey to somebody that it's only 1 to 2 percent,
5 which is less than the background risk for all birth
6 defects, does that convey the potency of this drug
7 when you ignore that it's a 2,060 percent increase for
8 spina bifida resulting from exposure to valproic acid?

9 MR. BALL: Object to the form and
10 foundation.

11 A. I think the relative risk and the percentage
12 extension of that or restatement of that is much more
13 meaningful in terms of communicating the increased
14 risk.

15 Q. (By Mr. Williams) Okay. And you were asked
16 some questions about you might disagree with a
17 statement that -- from the Spina Bifida Association.
18 Do you know whether that statement was intended for
19 physicians or it was intended for donors?

20 A. I have no idea.

21 Q. And they've -- have you received the lifetime
22 achievement award from the Spina Bifida Association?

23 A. I have.

24 Q. Is it important, sir, to be correct about